

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	1	of	6
-------	---	----	---

Complete if Known

Application Number	09/466,035
Filing Date	December 17, 1999
First Named Inventor	Sallberg
Art Unit	1633
Examiner Name	A. Wehbe
Attorney Docket Number	PP001231.0105 (002441.00249

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
/AW/		US- 6,384,018	02-2002	Content et al.	
		US- 5,814,617	09-1998	Hoffman et al.	
		US- 5,863,542	01-1999	Paoletti et al.	
		US- 5,753,258	05-1998	Schreier et al.	
		US- 5,755,602	06-16-1998	Xiong et al.	
		US- 5,589,466	12-31-1996	Felgner et al.	
		US- 6,210,663	04-03-2001	Ertl	
		US- 5,679,647	10-1997	Carson et al.	
		US- 6,110,898	08-2000	Malone et al.	
		US- 6,086,901	07-2000	O'Hagan et al.	
		US- 5,462,734	10-1995	Letchworth et al.	
		US- 2003/0021766	01-2003	Vajdy et al.	
		US- 5,843,723	12-01-1998	Dubensky et al.	
		US- 6,015,686	01-18-2000	Dubensky et al.	
		US- 6,015,694	01-18-2000	Dubensky et al.	
		US- 6,110,898	08-2000	Malone et al.	
		US- 6,261,570	07-2001	Parker et al.	
		US- 5,612,201	03-1997	De Plaen et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
/AW/		WO 00/44410	08-03-2000	Stichting Biomedical Primate Research Centre		
↓		WO 9747320 A1	12-1997	Schroeder, Ulf		
		WO 02/45741	06-2002	Del Giudice et al.		
		WO 92/11028A	07-09-1992	Ferro		
		WO 94/25601	11-10-1994	Maertens		
		WO 94/24267	10-27-1997	Robinson		

**Examiner
Signature**

Date Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 6

Complete if Known

Application Number	09/466,035
Filing Date	December 17, 1999
First Named Inventor	Sallberg
Art Unit	1633
Examiner Name	A. Wehbe
Attorney Docket Number	PP001231.0105 (002441.00249)

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
/AW/		Chapman et al. Nucleic Acid Research. 1991; 19: 3979-3986.	
		Wang et al. Virology. 1995; 211: 102-112.	
		Eldridge et al. Infection and Immunity. 1991; 59 (9): 2978-2986.	
		Pertmer et al. Vaccine. Oct. 1995; 13 (15): 1427-1430.	
		Doe et al. European Journal of Immunology. 1994; 24: 2369-2376.	
		Fields et al. Virology. 3rd ed. Philadelphia: Lippencott Williams and Wilkins; 1995, page 1885.	
		Klein et al. Clinical Therapeutics. 2000; 22 (3): 295-314) on pages 304-305.	
		Marshal: Gene therapy's grpwng pains: Science: Vol. 269: pp. 1050-1055 Aug 1995	
		Mulligan: The basic science of gene therapy: Science: Vol. 260:pp. 928-932 May 1993	
		Wang et al., "Mucosal immunization with a DNA vaccine induces immune responses against HIV-1 at a mucosal site," Vaccine 15:821-825, 1997.	
		BELYAKOV et al., "Induction of a mucosal cytotoxic T-lymphocyte response by intrarectal immunization with a replication-deficient recombinant vaccinia virus expressing human immunodeficiency virus 89.6 envelope protein", J. Virol. (1998), 72 (10): 8264-8272.	
↓		Rothel et al. "Sequential Nucleic Acid and Recombinant Adenovirus Vaccination Induces Host-Protective Immune Responses Against Taenia Ovis Infection in Sheep." Parasite Immunology. Vol. 19, no. 5, May 1997. p. 221-227.	

Examiner Signature	Date Considered
-----------------------	--------------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 3 of 6

Complete if Known

Application Number	09/466,035
Filing Date	December 17, 1999
First Named Inventor	Sallberg
Art Unit	1633
Examiner Name	A. Wehbe
Attorney Docket Number	PP001231.0105 (002441.00249)

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	1 ²
		Office ³	Number ⁴	Kind Code ⁵ (if known)			
AW	B1	WO	96/29412	A1	IAF Bio Vac Inc.	09-26-1996	
	B2	WO	99/24578	A2	Chiron S.P.A.	05-20-1999	
	B3	WO	99/36544	A2	Chiron S.P.A.	07-22-1999	
	B4	WO	99/57280	A2	Chiron Corporation	11-11-1999	
	B5	WO	99/61053	A1	Chiron Corporation	12-02-1999	
	B6	WO	00/11140	A1	The Wistar Institute of Anatomy and Biology	03-02-2000	
	B7	WO	00/22430	A2	Chiron Corporation	04-20-2000	
	B8	WO	00/39302	A2	Chiron Corporation	07-06-2000	
	B9	WO	00/50075	A2	Chiron S.P.A.	08-31-2000	
	B10	WO	00/66741	A2	Chiron S.P.A.	11-09-2000	
	B11	WO	00/66791	A1	Chiron Corporation	11-09-2000	
	B12	WO	00/71574	A2	Chiron S.P.A.	11-30-2000	
	B13	WO	00/71725	A2	Chiron S.P.A.	11-30-2000	
	B14	WO	01/04316	A2	Chiron S.P.A.	01-18-2001	
	B15	WO	01/31019	A1	Invitrogen Corporation	05-03-2001	
	B16	WO	01/37863	A2	Chiron S.P.A.	05-31-2001	
	B17	WO	01/38350	A2	Chiron S.P.A.	05-31-2001	
	B18	WO	01/52885	A1	Chiron S.P.A.	07-26-2001	
	B19	WO	01/64920	A2	Chiron S.P.A.	09-07-2001	
	B20	WO	01/64922	A2	Chiron S.P.A.	09-07-2001	
	B21	WO	01/81609	A2	Chiron Corporation	11-01-2001	

Examiner Signature	Date Considered
-----------------------	--------------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 4 of 6

Complete if Known

Application Number	09/466,035
Filing Date	December 17, 1999
First Named Inventor	Sallberg
Art Unit	1633
Examiner Name	A. Wehbe
Attorney Docket Number	PP001231.0105 (002441.00249)

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
/AW/	C1	BAGARAZZI et al., "Systemic and mucosal immunity is elicited after both intramuscular and intravaginal delivery of human immunodeficiency virus type 1 DNA plasmid vaccines to pregnant chimpanzees," J. Infect. Dis. 180:1351-1355, 1999	
	C2	BARRESINOUSI et al., "Isolation of a T-lymphotropic retrovirus from a patient at risk for acquired immune deficiency syndrome (AIDS)," Science 220:868-871, 1983	
	C3	BELYAKOV et al., "The importance of local mucosal HIV-specific CD8 cytotoxic T lymphocytes for resistance to mucosal viral transmission in mice and enhancement of resistance by local administration of IL-12," J. Clin. Invest. 102:2072-2081, 1998	
	C4	BRÜHL et al., "An experimental prime-boost regimen leading to HIV type 1-specific mucosal and systemic immunity in BALB/c mice," AIDS Research and Human Retroviruses 14:401-407, 1998	
	C5	CALEY et al., "Humoral, mucosal, and cellular immunity in response to a human immunodeficiency virus type 1 immunogen expressed by a Venezuelan equine encephalitis virus vaccine vector," J. Virology 71:3031-3038, 1997	
	C6	CLAVEL et al., "Isolation of a new human retrovirus from West African patients with AIDS," Science 233:343-346, 1986	
	C7	CLAVEL et al., "Molecular cloning and polymorphism of the human immune deficiency virus type 2," Nature 324:691-695, 1986	
	C8	COONEY et al., "Enhanced immunity to human immunodeficiency virus (HIV) envelope elicited by a combined vaccine regimen consisting of priming with a vaccinia recombinant expressing HIV envelope and boosting with gp160 protein," Proc. Natl. Acad. Sci. USA 90:1882-1886, 1993	
	C9	EO et al., "Prime-boost immunization with DNA vaccine: mucosal route of administration changes the rules," J. Immunology 166:3473-3479, 2001	
	C10	GARDNER et al., "Infection of human dendritic cells by a Sindbis virus replicon vector is determined by a single amino acid substitution in the E2 glycoprotein," J. Virology 74:11849-11857, 2000	
	C11	GRANOFF et al., "Bactericidal monoclonal antibodies that define unique Meningococcal B polysaccharide epitopes that do not cross-react with human polysialic acid," J. Immunology 160:2028-2036, 1998	

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 5 of 6

Complete if Known

Application Number	09/466,035
Filing Date	December 17, 1999
First Named Inventor	Sallberg
Art Unit	1633
Examiner Name	A. Wehbe
Attorney Docket Number	PP001231.0105 (002441.00249)

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
IAW/	C12	GUYADER et al., "Genome organization and transactivation of the human immunodeficiency virus type 2," Nature 326:662-669, 1987	
	C13	JENNINGS et al., "Induction of Meningococcal group B polysaccharide-specific IgG antibodies in mice by using an N-propionylated B polysaccharide-tetanus toxoid conjugate vaccine," J. Immunology 137:1703-1713, 1986	
	C14	JENNINGS et al., "N-propionylated group B Meningococcal polysaccharide mimics a unique epitope on group B Neisseria Meningitidis," J. Exp. Med. 165:1207-1211, 1987	
	C15	LEE et al., "Immunization of rhesus monkeys with a mucosal prime, parenteral boost strategy protects against infection with Helicobacter pylori," Vaccine 17:3072-3082, 1999	
	C16	LEVY et al., "Isolation of lymphocytotropic retroviruses from San Francisco patients with AIDS," Science 225:840-842, 1984	
	C17	MOINGEON, "Cancer vaccines," Vaccine 19:1305-1326, 2001	
	C18	MONTAGNIER et al., "A new human T-lymphotropic retrovirus: characterization and possible role in lymphadenopathy and acquired immune deficiency syndromes," in Human T-cell Leukemia/Lymphoma Virus, Gallo, Essex & Gross, eds., pp. 363-379, Cold Spring Harbor Laboratory, 1984	
	C19	POPOVIC et al., "Detection, isolation, and continuous production of cytopathic retroviruses (HTLV-III) from patients with AIDS and pre-AIDS," Science 224:497-500, 1984	
	C20	ROSENBERG, "Progress in human tumour immunology and immunotherapy," Nature 411:380-384, 2001	
	C21	STAATS et al., "Intranasal immunization is superior to vaginal, gastric, or rectal immunization for the induction of systemic and mucosal anti-HIV antibody responses," AIDS Research and Human Retroviruses 13:945-952, 1997	
↓	C22	VILMER et al., "Isolation of new lymphotropic retrovirus from two siblings with hHemophilia B, one with AIDS," The Lancet 1:753-757, 1984	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 6 of 6

Complete if Known

Application Number	09/466,035
Filing Date	December 17, 1999
First Named Inventor	Sallberg
Art Unit	1633
Examiner Name	A. Wehbe
Attorney Docket Number	PP001231.0105 (002441.00249)

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
/AW/		CAIRNS et al., "New Viral Vectors for HIV Vaccine Delivery," <i>Aids Research and Human Retroviruses</i> (Mary Ann Liebert, ed., US) (1998), 14 (17): 1501-1508.	
		HARIHARAN et al., "DNA Immunization against Herpes Simplex Virus: Enhanced Efficacy Using a Sindbis Virus-Based Vector," <i>J. Virol.</i> (1998), 72(3): 950-958.	
		KANO et al., "Induction of HIV-specific immune responses by using recombinant sendai viral vector," 7 th Conference on Retroviruses and Opportunistic Infections, [Online] 30 January 2000 - 2 February 2000, retrieval from the Internet < URL: http://www.retroconference.org/2000/abstracts/807.htm >, abstract 807 [retrieved on 2004-01-28].	
		POLO et al., "Stable alphavirus packaging cell lines for Sindbis virus- and Semliki Forest virus-derived vectors," <i>PNAS USA</i> (1999), 96: 4598-4603.	
		TSUJI et al., "Recombinant Sindbis Viruses Expressing a Cytotoxic T-Lymphocyte Epitope of a Malaria Parasite or of Influenza Virus Elicit Protection Against the Corresponding Pathogen in Mice," <i>J. Virol.</i> (1998), 72(8): 6907-10.	
		VAJDY et al., "Human Immunodeficiency Virus Type 1 Gag-Specific Vaginal Immunity and Protection After Local Immunizations with Sindbis Virus-Based Replicon Particles," <i>J. of Infect. Diseases</i> (2001), 184: 1613-1616.	
		Harcourt, G.C. "HIV-1 Variation Diminishes CD4 T Lymphocyte Recognition" <i>J. Exp. Med.</i> (1998) 188, 10, 1785-1793	
		VILLACRES et al., "Maintenance of CD8+ T-Cell Memory Following Infection with Recombinant Sindbis and Vaccinia Viruses," <i>Virology</i> (2000), 270: 54-64.	
		Hu et al. "Immunization with HIV-1 GP160 enhances HIV-specific immune responses elicited by vaccinia-HIV recombinant virus" 6 th International Conference on AIDS, 1990, San Francisco, page 205.	
		Bohm et al. "DNA vector constructs that prime hepatitis B surface antigen-specific cytotoxic T lymphocyte and antibody responses in mice after intramuscular injection" <i>Journal of Immunological Methods</i> , vol. 193, 14, June 1996. 29-40	
		Li et al. "Priming with recombinant influenza virus followed by administration of recombinant vaccinia virus induces CD8+ t-cell-mediated protective immunity against malaria." <i>PNAS</i> , vol. 90, 1993, 5214-5218.	
		Sallberg et al. "Characterization of humoral and CD4+ cellular responses after genetic immunization with retroviral vectors expressing different forms of the hepatitis B virus core and E antigens." <i>Journal of Virology</i> . Vol. 71, no. 7, July 1997. 5295-5303.	

Examiner Signature	/Anne Marie Wehbe/ (11/04/2007)	Date Considered	11/04/2007
--------------------	---------------------------------	-----------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.